DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-977/S-002
NDA 20-978/S-002

Glaxo Wellcome Inc. December 15, 2000
Attention: Martha Anne A. Moore, R.Ph.
Antiviral Group- Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications, dated December 16, 1999, received December 17, 1999, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Ziagen® (abacavir sulfate) Tablets and Oral Solution.

We acknowledge receipt of your submissions dated: March 24, 2000; May 15, 2000; May 31, 2000; June 5, 2000; August 25, 2000; November 7, 2000; and December 5, 2000. The user fee goal date for these applications is December 17, 2000.

These supplemental new drug applications contain 48-week data from Study CAAB3005 comparing abacavir plus lamivudine plus zidovudine to indinavir plus lamivudine plus zidovudine and the results from the methadone/abacavir drug interaction study for inclusion in the abacavir label.

We have completed the review of these supplemental new drug applications, as amended, according to the regulations for accelerated approval, and have concluded that adequate information has been presented to demonstrate that Ziagen® (abacavir sulfate) is safe and effective for use as recommended in the agreed upon draft labeling text dated December 5, 2000. Accordingly, these applications are approved on the date of this letter. Marketing of these drug products and related activities continue to be in accordance with the accelerated approval regulations (21 CFR 314 Subpart H).

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert, text for the medication guide and text for the warning card dated December 5, 2000). Marketing the product with FPL that is not identical to the submitted labeling may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten copies on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-NDAs* (January 1999). For administrative purposes these submissions should be designated "FINAL PRINTED LABELING" for approved supplement NDA 20-977 (S-002) and approved

supplement NDA 20-978 (S-002). Approval of these submissions by FDA is not required before the labeling is used.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that at this time you have fulfilled the pediatric study requirement for patients age 3 months to 16 years of age. In addition, we note that the requirement to study pediatric patients < 3 months of age has been waived.

We remind you that you must comply with the requirement for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have questions, please contact Ms. Melissa M. Truffa, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely yours,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research